

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

SYMED LABS LIMITED and HETERO USA, INC.,

Plaintiffs,

v.

ROXANE LABORATORIES, INC.,

Defendant

Civil Action No.:
2:15-cv-08304-CCC-MF
(LEAD DOCKET)

SYMED LABS LIMITED and HETERO USA, INC.,

Plaintiffs,

v.

GLENMARK PHARMACEUTICALS INC.,

Defendant

Civil Action No.
2:15-cv-08306-CCC-MF

SYMED LABS LIMITED and HETERO USA, INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS LLC,

Defendant

Civil Action No.
2:15-cv-08307-CCC-MF

**JOINT CLAIM CONSTRUCTION AND
PREHEARING STATEMENT**

Pursuant to District of New Jersey L. Pat. R. 4.3, and the Court's Sixth Amended Scheduling Order, Plaintiffs Symed Labs Limited and Hetero USA, Inc. (together "Symed" or "Plaintiffs"), together with Defendants Roxane Laboratories, Inc. ("Roxane"), Glenmark Pharmaceuticals Inc. ("Glenmark"), and Amneal Pharmaceuticals LLC ("Amneal") hereby

provide their Joint Claim Construction and Prehearing Statement concerning U.S. Patent Nos. 7,714,128 (“the ’128 patent”), 7,732,597 (“the ’597 patent”) and 7,718,799 (“the ’799 patent”).

I. LOCAL PATENT RULE 4.3(a) – CONSTRUCTION OF TERMS ON WHICH THE PARTIES AGREE

In accordance with L. Pat. R. 4.3(a), the parties have met and conferred pursuant to Local Patent Rule 4.2 and agree that the following terms should be construed as follows:

Claim	Term	Parties’ Construction
’597: 1	“comprises the steps of”	Plain meaning, i.e., which has at least the following steps or limitations.
’799: 1	“which comprises”	Plain meaning, i.e., which has at least the following steps or limitations.

The parties wish to clarify that the foregoing agreed upon meanings by no means exclude Plaintiffs’ position that these terms be construed as part of certain grouped terms/entire phrases, which interpretation Defendants dispute as will be explained below.

II. LOCAL PATENT RULE 4.3 (b) – PROPOSED CONSTRUCTION OF DISPUTED CLAIM TERMS

In accordance with L. Pat. R. 4.3(b), each party’s proposed construction for claim terms on which they disagree is set forth below. As required by Local Patent Rule 4.3(b), the table of Exhibit A attached hereto identifies the intrinsic and extrinsic evidence that each party intends to rely on in support of its respective constructions, or to oppose the opposing party’s proposed constructions.

Parties' Proposed Constructions of Disputed Terms:

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
'128: 1, 2	"A crystalline linezolid form III"	<i>A new crystalline form of linezolid that is different from prior known crystalline forms I and II.</i>	<i>A crystalline linezolid polymorph that demonstrates each and every one of the claimed XRPD 2θ values and IR bands</i>
'128: 1, 2 '597: 1 '799: 1	"about" preceding the XRPD spectrum values	<i>approximately</i> <i>Plaintiffs assert that this term qualifies and should be construed as part of the overall spectrum of XRPD values following it</i>	<i>Indefinite</i> <i>Alternatively, if the Court determines this term is amenable to construction: no more than a +/- 0.1 degree variance</i>
'128: 1, 2 '799: 1	"about" preceding the IR spectrum band values	<i>approximately</i> <i>Plaintiffs assert that this term qualifies and should be construed as part of the overall spectrum of XRPD values following it</i>	<i>Indefinite</i> <i>Alternatively, if the Court determines this term is amenable to construction: a scientifically acceptable margin of error</i>
'128: 1	"enantiomeric excess of the linezolid form III"	<i>ee: plain and ordinary meaning, i.e., $ee = ((R-S)/(R+S) \times 100$</i> <i>form III: see preamble of claims 1 and 2.</i>	<i>Indefinite</i>

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
'128: 1, 2 '597: 1 '799: 1	"characterized by"	<i>Comprising</i>	<i>which must include</i>
'128: 1, 2 '799: 1	"having peaks"	<i>including peaks</i>	<i>having each and every one of the peaks</i>
'128: 1, 2	"and further characterized by"	<i>and further comprising</i>	<i>and which must also include</i>
'799: 1	"is further characterized by"	<i>and further comprising</i>	<i>must also include</i>
'128: 1, 2 '799: 1	"having main bands"	<i>including the following main bands</i>	<i>having each and every one of the recited main bands</i>
'597: 1	"having 2 θ angle positions"	<i>including 2θ angle positions</i>	<i>having each and every one of the 2θ angle positions</i>
'128: 1, 2	"characterized by an x-ray powder diffraction having peaks expressed as 2 θ at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees"	<i>comprising an x-ray powder diffraction spectrum including 2θ peaks at approximately 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9, and 29.9 degrees, wherein each peak has a built-in error margin of +/-0.2 degrees</i>	<p>Defendants believe that this long phrase is not a single term and does not need to be separately construed in light of the Court's construction of the terms "characterized by," "having peaks," and "about" preceding the XRPD spectrum values</p> <p>However, if the Court holds that this phrase is not indefinite and must be construed together without separating</p>

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
			the individual terms, Defendants propose the following construction: <i>which must include an x-ray powder diffraction having each and every one of the peaks expressed as 2θ at 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees +/- 0.1 degree variance.</i>
'128: 1, 2	“and further characterized by an IR spectrum having main bands at about 3338, 1742, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm ⁻¹ ”	<i>and further comprising an IR spectrum including main bands at approximately 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm⁻¹, wherein each band has a built-in error margin of +/- 0.1-10 cm⁻¹</i>	<p>Defendants believe that this long phrase is not a single term and does not need to be separately construed in light of the Court's construction of the terms “and further characterized by”, “having main bands”, and “about” preceding the IR spectrum band values</p> <p>However, if the Court holds that this phrase is not indefinite and must be construed together without separating the individual terms, Defendants propose the following construction: <i>and which must also include an IR spectrum having each and every one</i></p>

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
			<i>of the recited main bands at 3338, 1742, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm-1 within a scientifically acceptable margin of error.</i>
'799:1	“is further characterized by an IR spectrum having main bands at about 3338, 1742, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm-1”	<i>further comprising an IR spectrum including main bands at approximately 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm-1, wherein each band has a built-in error margin of +/- 0.1-10 cm-1</i>	<p>Defendants believe that this long phrase is not a single term and does not need to be separately construed in light of the Court's construction of the terms “is further characterized by”, “having main bands”, and “about” preceding the IR spectrum band values</p> <p>However, if the Court holds that this phrase is not indefinite and must be construed together without separating the individual terms, Defendants propose the following construction: <i>must also include an IR spectrum having each and every one of the recited main bands at 3338, 1742,</i></p>

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
			1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm ⁻¹ within a scientifically acceptable margin of error.
'597: 1	"A process for preparation of linezolid form III, characterized by peaks in the powder x-ray diffraction spectrum having 2θ angle positions at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees"	<i>A method for preparing a crystalline form of linezolid that is different from prior known crystalline forms I and II, comprising an x-ray powder diffraction spectrum including 2θ peaks at approximately 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9, and 29.9 degrees, wherein each peak has a built-in error margin of +/-0.2 degrees</i>	<p>Defendants believe that this long phrase is not a single term and does not need to be separately construed in light of the Court's construction of the terms "characterized by," "having 2θ angle positions," and "about" preceding the XRPD spectrum values.</p> <p>However, if the Court holds that this phrase is not indefinite and must be construed together without separating the individual terms, Defendants propose the following construction: <i>A process for preparation of crystalline linezolid polymorph which must include peaks in the powder x-ray diffraction having each and every one</i></p>

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
			<i>of the 2θ angle positions at 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees +/- 0.1 degree variance</i>
'799: 1	<p>“A process for preparation of linezolid form III characterized by an x-ray powder diffraction spectrum having peaks expressed as 2θ at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees, wherein the crystalline linezolid form III is further characterized by an IR spectrum having main bands at about 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm⁻¹”</p>	<p><i>A method for preparing a crystalline form of linezolid that is different from prior known crystalline forms I and II, comprising an x-ray powder diffraction spectrum including 2θ peaks at approximately 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9, and 29.9 degrees, wherein each peak has a built-in error margin of +/-0.2 degrees; and comprising an IR spectrum including bands at approximately 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm⁻¹ (+/- 0.1-10 cm⁻¹)</i></p>	<p>Defendants believe that this long phrase is not a single term and does not need to be separately construed in light of the Court's construction of the terms “characterized by”, “having peaks,” “is further characterized by,” “having main bands,” “about” preceding the XRPD spectrum values, and “about” preceding the XRPD spectrum values and IR spectrum values.</p> <p>However, if the Court holds that this phrase is not indefinite and must be construed together without separating the individual terms, Defendants propose the following construction: <i>A process for preparation of linezolid form III which must include an x-powder diffraction spectrum having each and every one of the peaks expressed as 2θ at 7.6, 9.6, 13.6,</i></p>

Claim	Term	Plaintiffs' Proposed Construction	Defendants' Proposed Construction
			<p><i>14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees +/- 0.1 degree variance, wherein the crystalline linezolid form III must include an IR spectrum having each and every one of the main bands at 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm⁻¹ with a scientifically acceptable margin of error</i></p>

III. LOCAL PATENT RULE 4.3(c) – SIGNIFICANT OR DISPOSITIVE CLAIM TERMS

In accordance with L. Pat. R. 4.3(c), the Parties believe construction of the following terms will be most significant to the resolution of the case, even if not ultimately dispositive of issues in the cases.

Plaintiffs' Disclosure:

Plaintiffs believe construction of the following claim terms will be the most significant in this case; however, Plaintiffs do not believe the construction of any term will necessarily be dispositive of the outcome.

Patent in Suit	Claim Term
'128 patent, claims 1 and 2 preamble	crystalline linezolid form III
'128 patent, claims 1 and 2 '597 patent, claim 1 preamble '799 patent, claim 1 preamble	having peaks expressed as 2θ at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees,
'128 patent, claims 1 and 2 '799 patent, claim 1 preamble	having main bands at about 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm ⁻¹

Defendants' Disclosure:

Defendants believe that the construction of the following terms will be most significant to the resolution of the case. Depending on the construction adopted by the Court, the following terms may also be case dispositive.

Patent	Term
'128: 1, 2 '597: 1 '799: 1	“about” preceding the XRPD spectrum values
'128: 1, 2 '799: 1	“about” preceding the IR spectrum band values
'128: 1, 2 '799: 1	“having peaks”
'128: 1, 2 '799: 1	“having main bands”
'597: 1	“having 2 θ angle positions”

IV. LOCAL PATENT RULE 4.3(d) – ANTICIPATED LENGTH OF CLAIM CONSTRUCTION HEARING

In accordance with L. Pat. R. 4.3(d), the parties anticipate that the Claim Construction Hearing, including argument and any witness testimony, can be completed in one day.

V. LOCAL PATENT RULE 4.3(e) – IDENTIFICATION OF ANTICIPATED WITNESSES FOR CLAIM CONSTRUCTION HEARING

In accordance with L. Pat. R. 4.3(e), the parties identify the following witnesses and anticipated testimony to be offered related to claim construction.

Plaintiffs' Disclosure:

Plaintiffs have no present intention to call any witness to provide live testimony at the claim construction hearing, but reserve the right to do so. Plaintiffs may rely on live rebuttal or

other expert testimony in support of or in opposition to any proposed claim construction of any Defendant that differs from that of Plaintiffs, and for which such Defendant relies upon expert or other testimony.

Defendants' Disclosure:

Defendants reserve the right to call any witness to provide live testimony at the claim construction hearing. Defendants may rely on live expert testimony in support of their proposed claim construction and/or in opposition to Plaintiffs' proposed claim construction. Specifically, Defendants may rely on a chemist and/or material scientist with expertise in infrared spectroscopy and x-ray powder diffraction to provide testimony as outlined in the attached Exhibit A.

Joint Statement of Parties Regarding Expert Testimony:

Plaintiffs and Defendants acknowledge that all Parties have reserved the right to rely on expert testimony in support of their proposed claim constructions and/or in opposition to proposed constructions and/or supporting evidence of other Parties. While the Parties have not, in attached Exhibit A, provided the name(s) or declarations of the expert(s) who may provide testimony, all Parties agree to allow initial disclosure of the identity of claim construction experts and their declarations to be made with the Parties' opening claim construction briefs. The Parties respectfully request the Court's guidance as to the intent of the Local Patent Rules as they relate to the use of expert testimony in responsive *Markman* briefing by a party that has not relied on expert testimony in opening *Markman* briefing and ask that this be an issue addressed by the Court at the upcoming January 20, 2017 status conference.

Date: January 17, 2017

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EXHIBIT A

U.S. PATENT NO. 7,714,128

Claim term	Plaintiffs' Construction and Evidence	Defendants' Construction and Evidence
<p>"A crystalline linezolid form III"</p> <p>Preamble in claims 1 and 2</p>	<p>CONSTRUCTION</p> <p><i>A new crystalline form of linezolid that is different from prior known crystalline forms I and II.</i></p> <p>EVIDENCE</p> <p><i>See, e.g., '128 patent, col. 1, lines 53-62.</i></p> <p>Plaintiffs' Responses to Defendants' Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by Plaintiffs in regard to the Preamble in claims 1 and 2 "A crystalline linezolid form III," or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject matter or any other term(s) in claims of the '128 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the Preamble in claims 1 and 2 "A crystalline linezolid form III" of the '128 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p>	<p>CONSTRUCTION</p> <p><i>A crystalline linezolid polymorph that demonstrates each and every one of the claimed XRPD 2θ values and IR bands</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> '128 Patent, claims 1 and 2 '128 Patent specification, including: <ul style="list-style-type: none"> Col. 2, ll. 3-14 Col. 3, ll. 20-28 File History of U.S. Pat. Application No. 10/524,478, including: <ul style="list-style-type: none"> Claims of U.S. Patent Application 10/524,478 [original claims] 11/08/2007 Non-Final Rejection 2/4/2008 Amendment 05/22/2008 Final Rejection 08/20/2008 Amendment 10/10/2008 Non-Final Rejection 11/20/2008 Amendment 03/19/2009 Final Rejection 06/04/2009 Amendment 08/21/2009 Final Rejection 12/04/2009 Amendment 03/24/2010 Notice of Allowance One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term "[a] crystalline linezolid form III." The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation should be construed to mean a crystalline linezolid polymorph that demonstrates each and every one of the claimed XRPD 2θ values and IR bands. For example, the expert(s) may testify

	<p>Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the terminology "having peaks" in claims 1 and 2 of the '128 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively "Additional Disclosures"), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by</p>	<p>that consistent with at least the prosecution history and/or knowledge of customary usage by those of ordinary skill in the art and/or the cited extrinsic evidence all recited peaks XRPD peaks and IR bands should be present for a given polymorph. The expert(s) may also rebut arguments presented by Plaintiffs' expert(s).</p> <ul style="list-style-type: none"> • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition an/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants' Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs' Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	
<p>“about”</p> <p>preceding the XRPD spectrum values in claims 1 and 2</p>	<p>CONSTRUCTION <i>approximately</i></p> <p><i>Plaintiffs assert that this term qualifies and should be construed as part of the overall spectrum of XRPD values following it</i></p> <p>EVIDENCE <i>See, e. g., '128 patent, col. 2., lines 6-9; col. 3, lines 20-23; col.6, lines 2-5.</i></p> <p><i>See, e.g., '128 USPTO file history, PLJ0000104-536 and more specifically PLJ0000402; PLJ0000439-444 and PLJ0000445-454; PLJ0000475-480 and PLJ0000481-497 especially PLJ0000486, 492 and 497</i></p> <p>H. G. Brittain, Ed., Polymorphism in Pharmaceutical Solids, p.236, (Marcel Dekker, Inc. 1999), LINEZ-JDG-00000446-449; PLJ0001868-1893, 1891.</p>	<p>CONSTRUCTION <i>Indefinite</i></p> <p>Alternatively, if the Court determines this term is amenable to construction: <i>no more than a +/- 0.1 degree variance</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • '128 Patent, claims 1 and 2 • '128 Patent specification, including: <ul style="list-style-type: none"> o Col. 2, ll. 6-9 o Col. 3, ll. 20-23 • File History of U.S. Pat. Application No. 10/524,478, including: <ul style="list-style-type: none"> o Claims of U.S. Patent Application 10/524,478 [original claims] o 11/08/2007 Non-Final Rejection o 2/4/2008 Amendment o 05/22/2008 Final Rejection o 08/20/2008 Amendment o 10/10/2008 Non-Final Rejection o 11/20/2008 Amendment o 03/19/2009 Final Rejection

<p>Brittain, H. Profiles of Drug Substances Excipients, 30: 273-319, 2003, esp. 302-303, PLJ0001925-1948.</p> <p>Brittain, H., Spectroscopy, 16(7): 2001_Harry G. Brittain, PLJ0001917-1921.</p> <p>WO 2011139414 A2, PLJ0001828-1861.</p> <p>U.S. Pharmacopoeia 23 General Ch. 941, PLJ0001803-1804; LINEZ-JDG-00003607-3610.</p> <p>U.S. Pharmacopoeia 26 General Ch. 941, PLJ0001922-1924; LINEZ-JDG-00003615-3619.</p> <p>U.S. Pharmacopoeia 29 General Ch. 941, PLJ0001824-1827.</p> <p>R. Jenkins, R. Snyder, Introduction to X-ray Powder Diffractometry, p. 254-55 (John Wiley & Sons, Inc. 1996), PLJ0001894-1908, 1907-1908.</p> <p>Maccaroni, E. et al, Int. J. Pharm. 351 :144-151 (2008), PLJ0001949-1956.</p> <p>Wielgus, E. et al, J. Pharm. Sci. (2015), 104(11), 3883-3892 and its Supplemental Information, PLJ0001957-1966.</p> <p>Plaintiffs' Responses to Defendants' Invalidity Contentions at 31, dated Nov. 4, 2016</p> <p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person</p>	<ul style="list-style-type: none"> ○ 06/04/2009 Amendment ○ 08/21/2009 Final Rejection ○ 12/04/2009 Amendment ○ 03/24/2010 Notice of Allowance • Polymorphism in Pharmaceutical Solids Drugs, "<i>Methods for the Characterization of Polymorphs and Solvates</i>," Brittain, H., ed., Marcel Dekker, New York, Chapter 6, 236, 227-278, (1999) (LINEZ-JDG-00000008-59). • USP 23 at 1843-44 (LINEZ-JDG-00003607-3610). • USP 26 at 2233-34 (LINEZ-JDG-00003611-3614). • USP 28 at 2514 (LINEZ-JDG-00003615-3619). • One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term "about" preceding the XRPD spectrum values in claims 1 and 2. The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is indefinite and/or means no more than a +/- 0.1 degree variance. For example, the expert(s) may testify that consistent with at least the USP and/or knowledge of customary usage by those of ordinary skill in the art 0.1 is the acceptable margin of error of XRPD spectrum values. The expert(s) may also rebut arguments presented by Plaintiffs' expert(s). • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the term “about” as used in the claims of the ’128 Patent would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants’ proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p> <p>Plaintiffs’ expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the term “about” preceding the XRPD spectrum values, including as used in the claims of the ’128 Patent, and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants’ construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs’ construction of the subject term or any other term(s) in claims of the ’128 patent or of any other patent in suit.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in</p>	
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	<p>the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants’ Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs’ Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	
<p>“about” preceding the IR spectrum band</p>	<p>CONSTRUCTION <i>approximately</i></p>	<p>CONSTRUCTION <i>Indefinite</i> Alternatively, if the Court determines this term is amenable to construction:</p>

<p>values in claims 1 and 2</p>	<p><i>Plaintiffs assert that this term qualifies and should be construed as part of the overall spectrum of IR main band values following it</i></p> <p>EVIDENCE <i>See, e.g., '128 patent, col. 2, lines 10-14; col. 3, lines 24-28.</i></p> <p><i>See, e.g., '128 file history, PLJ0000439-454, esp. PLJ0000441, 450-451.</i></p> <p>R. Nyquist et. al., The Handbook of Infrared and Raman Spectra of Inorganic Compounds and Organic Salts, Vol. 1, p. 2 (Academic Press 1997), PLJ0001862-1863.</p> <p>H. Szymanski, Ed., Infrared Band Handbook, p. vii-viii (Plenum Press 1963), PLJ0001864-1867</p> <p>U.S. Pharmacopoeia 37 General Ch. 851, PLJ0001911-1916; U.S. Pharmacopoeia 23 General Ch. 851 LINEZ-JDG-3337-3344.</p> <p>WO 2007/018588, PLJ0002029-2084.</p> <p>US Patent Appln Publication 2006/0142283 A1, PLJ0002005-2028.</p> <p>US Patent 5,688,792, LINEZ-JDG-00000682-694.</p> <p>US Patent 6,444,813, LINEZ-JDG-00000828-831.</p> <p>US Patent 6,559,305, LINEZ-JDG-00000674-677.</p>	<p><i>a scientifically acceptable margin of error</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • '128 Patent, claims 1 and 2 • '128 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 2, ll. 10-14 ○ Col. 3, ll. 24-28 • File History of U.S. Pat. Application No. 10/524,478, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 10/524,478 [original claims] ○ 11/08/2007 Non-Final Rejection ○ 2/4/2008 Amendment ○ 05/22/2008 Final Rejection ○ 08/20/2008 Amendment ○ 10/10/2008 Non-Final Rejection ○ 11/20/2008 Amendment ○ 03/19/2009 Final Rejection ○ 06/04/2009 Amendment ○ 08/21/2009 Final Rejection ○ 12/04/2009 Amendment ○ 03/24/2010 Notice of Allowance • Plaintiffs' Responses to Defendants' Invalidity Contentions at 31, dated Nov. 4, 2016. • Drugs and the Pharmaceutical Sciences, "Spectroscopy in Pharmaceutical Solids," Bugay, D. and Brittain, H., Taylor and Francis, New York, Chapter 8, 235-270, (2006) (LINEZ-JDG-00000060-95). • Preformulation in Solid Dosage Form Development, "Spectroscopic Methods for the Characterization of Drug Substances," Adeyeye, M and Brittain, H., eds., CRC Press, Chapter 3.5, 253-277 (2008) (LINEZ-JDG-00003396-3420).
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<p>Brickner, S. et al., J. Med. Chem., 39(3), 673-9 (1996), PLJ0002085-91..</p> <p>US Patent 7,714,128, claims 1 and 2</p> <p>Wielgus, E. et al, J. Pharm. Sci. (2015), 104(11), 3883-3892 and its Supplemental Information, PLJ0001967-1994.</p> <p>Frelek, J. et al., Chem. Comm. (2012), 48(43), 5295-5297 and its Supplemental Information, PLJ0001995-2004.</p> <p>Drugs and the Pharmaceutical Sciences, “Spectroscopy in Pharmaceutical Solids,” Bugay, D. and Brittain, H., Taylor and Francis, New York, Chapter 8, 235-270, (2006) (LINEZ-JDG-00000060-95).</p> <p>Plaintiffs’ Responses to Defendants’ Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs may also rely, in opposition to Defendants’ construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the term “about” as used in the claims of the ’128 Patent would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants’ proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p>	<ul style="list-style-type: none"> • Polymorphism in Pharmaceutical Solids Drugs, “Methods for the Characterization of Polymorphs and Solvates,” Brittain, H., ed., Marcel Dekker, New York, Chapter 6, 227-278 (1999) (LINEZJDG- 00000008-59). • USP 23 at 1834 (LINEZ-JDG-00003337-3344). • USP 39 at 718-19 (LINEZ-JDG-00003602-3606). • One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term “about” preceding the IR spectrum band values in claims 1 and 2. The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is indefinite and/or means a scientifically acceptable margin of error. For example, the expert(s) may testify that consistent with at least the USP and/or knowledge of customary usage by those of ordinary skill in the art, the scientifically acceptable margin of error of IR spectrum values depends on various parameters in the sample preparation and measurements. The expert(s) may also rebut arguments presented by Plaintiffs’ expert(s). • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>Plaintiffs’ expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the term “about” preceding the IR spectrum band values, including as used in the claims of the ’128 Patent, and how such understanding of “about” would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants’ construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs’ construction of the subject term or any other term(s) in claims of the ’128 patent or of any other patent in suit.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly</p>	
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	<p>presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants’ Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs’ Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	
<p>“enantiomeric excess of the linezolid form III”</p> <p>in claim 1</p>	<p>CONSTRUCTION <i>Plain and ordinary meaning, i.e., $ee = ((R-S)/(R+S)) \times 100$</i></p> <p><i>Form III: see construction of preamble</i></p> <p>EVIDENCE <i>See, e.g., Organic Chemistry 4e Carey, Francis, Chapter 7, Stereochemistry, Optical Purity, Online Learning Center, McGraw-Hill 2000, http://www.mhhe.com/physsci/chemistry/carey/student/olc/ch07optical_activity.html, PLJ0001909-1910.</i></p>	<p>CONSTRUCTION <i>Indefinite.</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • ’128 Patent, claim 1 • ’128 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 3, ll. 40-42 ○ Example 2, Col. 4, ll. 57-60 • File History of U.S. Pat. Application No. 10/524,478, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 10/524,478 [original claims] ○ 11/08/2007 Non-Final Rejection

	<p>Plaintiffs' Responses to Defendants' Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '128 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the terminology "enantiomeric excess of the linezolid form III" in claim 1 of the '128 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p> <p>Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the terminology "enantiomeric excess of the linezolid form III" in claim 1 of the '128 Patent and how such understanding would be contrary to</p>	<ul style="list-style-type: none"> ○ 2/4/2008 Amendment ○ 05/22/2008 Final Rejection ○ 08/20/2008 Amendment ○ 10/10/2008 Non-Final Rejection ○ 11/20/2008 Amendment ○ 03/19/2009 Final Rejection ○ 06/04/2009 Amendment ○ 08/21/2009 Final Rejection ○ 12/04/2009 Amendment ○ 03/24/2010 Notice of Allowance • Preformulation in Solid Dosage Form Development, "Spectroscopic Methods for the Characterization of Drug Substances," Adeyeye, M and Brittain, H., eds., CRC Press, Chapter 3.5, 253, 253–277 (2008) (LINEZ-JDG-00003396-3420). • Polymorphism in Pharmaceutical Solids, <i>Methods for the Characterization of Polymorphs and Solvates</i>, Brittain, H., ed., Marcel Dekker, New York, Chapter 6, 228, 227-278 (1999) (LINEZJDG-00000008-59). • Organic Chemistry, "Isomerism," Brown, W. and Foote, C., Saunders College Publishing, Chapter 4.1, 120, 119-156, Second Edition, (1998) (LINEZ-JDG-00003478-3517). • Organic Chemistry, "Optical Activity," Peter, K et al., W. H. Freeman and Company Saunders College Publishing, Chapter 5, 172, 165-210, Third Edition, (1998) (LINEZ-JDG-00003518-3566). • One or more experts with a background in chemistry and/or material science may provide testimony that the term "enantiomeric excess of the linezolid form III" is indefinite. The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is
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	<p>any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or</p>	<p>indefinite. For example, the expert(s) may testify that consistent knowledge of customary usage by those of ordinary skill in the art and/or the cited extrinsic evidence references enantiomer excess refers to the purity of chiral molecules, not different polymorphs. The expert(s) may also rebut arguments presented by Plaintiffs’ expert(s).</p> <ul style="list-style-type: none"> • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	in connection with Defendants' Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs' Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).	
"characterized by" in claims 1 and 2	<p>CONSTRUCTION <i>comprising</i></p> <p>EVIDENCE <i>See, e. g., '128 patent, col. 2., lines 6-9; col. 3, lines 20-23; col.6, lines 2-5.</i></p> <p><i>See, e.g., '128 file history PLJ0000475-497, esp. PLJ0000487.</i></p> <p>Plaintiffs' Responses to Defendants' Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '128 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the terminology "characterized by" in claims 1 and 2 of the '128 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to</p>	<p>CONSTRUCTION <i>which must include</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • '128 Patent, claims 1 and 2 • '128 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 2, ll. 6-9 ○ Col. 3, ll. 20-23 • File History of U.S. Pat. Application No. 10/524,478, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 10/524,478 [original claims] ○ 11/08/2007 Non-Final Rejection ○ 2/4/2008 Amendment ○ 05/22/2008 Final Rejection ○ 08/20/2008 Amendment ○ 10/10/2008 Non-Final Rejection ○ 11/20/2008 Amendment ○ 03/19/2009 Final Rejection ○ 06/04/2009 Amendment ○ 08/21/2009 Final Rejection ○ 12/04/2009 Amendment ○ 03/24/2010 Notice of Allowance • One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term "characterized by." The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by

<p>that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p> <p>Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the terminology "characterized by" in claims 1 and 2 of the '128 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively "Additional Disclosures"), should the Court determine to consider</p>	<p>those of ordinary skill in the art, this claim limitation means which must include. For example, the expert(s) may testify that consistent with at least the prosecution history and/or knowledge of customary usage by those of ordinary skill in the art, the XRPD spectrum of a given polymorph must have the recited XRPD peaks of that polymorph. The expert(s) may also rebut arguments presented by Plaintiffs' expert(s).</p> <ul style="list-style-type: none"> • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants' Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs' Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	
<p>"having peaks" in claims 1 and 2</p>	<p>CONSTRUCTION <i>including peaks</i></p> <p>EVIDENCE <i>See, e. g., '128 patent, col. 2., lines 6-9; col. 3, lines 20-23; col.6, lines 2-5.</i></p> <p><i>See, e.g., '128 file history PLJ0000475-497, esp. PLJ0000487.</i></p> <p>Symed EPO Appeal, LINEZ-JDG-00002135-2179; LINEZ-JDG-00002201-2207.</p> <p>Plaintiffs' Responses to Defendants' Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by</p>	<p>CONSTRUCTION <i>having each and every one of the peaks</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • '128 Patent, claims 1 and 2 • '128 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 1, ll. 37-52 ○ Col. 2, ll. 6-9 ○ Col. 3, ll. 20-23 • File History of U.S. Pat. Application No. 10/524,478, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 10/524,478 [original claims] ○ 11/08/2007 Non-Final Rejection ○ 02/04/2008 Amendment ○ 05/22/2008 Final Rejection ○ 08/20/2008 Amendment ○ 10/10/2008 Non-Final Rejection

<p>Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '128 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the terminology "having peaks" in claims 1 and 2 of the '128 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p> <p>Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the terminology "having peaks" in claims 1 and 2 of the '128 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the</p>	<ul style="list-style-type: none"> ○ 11/20/2008 Amendment ○ 03/19/2009 Final Rejection ○ 06/04/2009 Amendment ○ 08/21/2009 Final Rejection ○ 12/04/2009 Amendment ○ 03/24/2010 Notice of Allowance • Ann W. Newman and G. Patrick Stahly, Form Selection of Pharmaceutical Compounds, Marcel Decker (2002) (LINEZ-JDG-00003421-3477). • Harry G. Brittain, Profiles of Drug Substances, Excipients and Related Methodology, Vol. 30, (2003) (LINEZ-JDG-00003620-3668). • One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term "having peaks." The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation means having each and every one of the peaks. For example, the expert(s) may testify that consistent with at least the prosecution history and/or knowledge of customary usage by those of ordinary skill in the art, all claimed XRPD peaks should be present for a given polymorph. The expert(s) may also rebut arguments presented by Plaintiffs' expert(s). • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants’ Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs’ Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	
“and further characterized by”	<p>CONSTRUCTION <i>and further comprising</i></p>	<p>CONSTRUCTION <i>and which must also include</i></p>

<p>in claims 1 and 2</p>	<p>EVIDENCE <i>See, e.g.</i>, '128 patent, col. 2, lines 10-14; col. 3, lines 24-28.</p> <p><i>See e.g.</i>, '128 file history, PLJ0000439-454, esp. PLJ0000441, 450-451.</p> <p>Plaintiffs' Responses to Defendants' Invalidity Contentions dated Nov. 4, 2016.</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '128 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the terminology "and further characterized by" in claims 1 and 2 of the '128 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p>	<p>EVIDENCE</p> <ul style="list-style-type: none"> • '128 Patent, claims 1 and 2 • '128 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 2, ll. 10-14 ○ Col. 3, ll. 24-28 • File History of U.S. Pat. Application No. 10/524,478, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 10/524,478 [original claims] ○ 11/08/2007 Non-Final Rejection ○ 02/04/2008 Amendment ○ 05/22/2008 Final Rejection ○ 08/20/2008 Amendment ○ 10/10/2008 Non-Final Rejection ○ 11/20/2008 Amendment ○ 03/19/2009 Final Rejection ○ 06/04/2009 Amendment ○ 08/21/2009 Final Rejection ○ 12/04/2009 Amendment ○ 03/24/2010 Notice of Allowance • One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term "and further characterized by." The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation means and which must also include. For example, the expert(s) may testify that consistent with at least the prosecution history and/or knowledge of customary usage by those of ordinary skill in the art, the IR spectrum of a given polymorph must
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	<p>Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the terminology "and further characterized by" in claims 1 and 2 of the '128 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively "Additional Disclosures"), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by</p>	<p>have the recited IR bands of that polymorph. The expert(s) may also rebut arguments presented by Plaintiffs' expert(s).</p> <ul style="list-style-type: none"> • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition an/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants' Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs' Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	
<p>“having main bands”</p> <p>in claims 1 and 2</p>	<p>CONSTRUCTION <i>including the following main bands</i></p> <p>EVIDENCE <i>See e.g., '128 patent, col. 2, lines 10-14; col. 3, lines 24-28.</i></p> <p><i>See e.g., '128 file history, PLJ0000439-454, esp. PLJ0000441, 450-451.</i></p> <p>Plaintiffs' Responses to Defendants' Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '128 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more</p>	<p>CONSTRUCTION <i>having each and every one of the recited main bands</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • '128 Patent, claims 1 and 2 • '128 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 1, ll. 37-52 ○ Col. 2, ll. 10-14 ○ Col. 3, ll. 24-28 • File History of U.S. Pat. Application No. 10/524,478, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 10/524,478 [original claims] ○ 11/08/2007 Non-Final Rejection ○ 02/04/2008 Amendment ○ 05/22/2008 Final Rejection ○ 08/20/2008 Amendment ○ 10/10/2008 Non-Final Rejection ○ 11/20/2008 Amendment ○ 03/19/2009 Final Rejection ○ 06/04/2009 Amendment ○ 08/21/2009 Final Rejection ○ 12/04/2009 Amendment

<p>experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the terminology “having main bands” in claims 1 and 2 of the ’128 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants’ proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p> <p>Plaintiffs’ expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the terminology “having main bands” in claims 1 and 2 of the ’128 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made</p>	<ul style="list-style-type: none"> ○ 03/24/2010 Notice of Allowance • Puligandla Viswanadham and Pratap Singh, FAILURE MODES AND MECHANISMS IN ELECTRONIC PACKAGES, at 114 (1998) (LINEZ-JDG-00003345-3395). • Phillip Crews et al., ORGANIC STRUCTURE ANALYSIS, Oxford University Press, at 329 (1998) (LINEZ-JDG-00003567-3601). • One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term “having main bands.” The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation means having each and every one of the recited main bands. For example, the expert(s) may testify that consistent with at least the prosecution history and/or knowledge of customary usage by those of ordinary skill in the art, all distinctive IR bands should be present for a given polymorph. The expert(s) may also rebut arguments presented by Plaintiffs’ expert(s). • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants’ Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs’ Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	
<p>“characterized by an x-ray powder diffraction having peaks expressed as 2θ at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees”</p> <p>in claims 1 and 2</p>	<p>CONSTRUCTION <i>comprising an x-ray powder diffraction spectrum including 2θ peaks at approximately 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9, and 29.9 degrees, wherein each peak has a built-in error margin of ± 0.2 degrees</i></p> <p>EVIDENCE <i>See, e. g., ’128 patent, col. 2., lines 6-9; col. 3, lines 20-23; col.6, lines 2-5.</i></p>	<p>CONSTRUCTION Defendants believe that this long phrase is not a single term and does not need to be separately construed in light of the Court’s construction of the terms “characterized by,” “having peaks,” and “about” preceding the XRPD spectrum values.</p> <p>However, if the Court holds that this phrase is not indefinite and must be construed together without separating the individual terms, Defendants propose the following construction: <i>which must include an x-ray powder diffraction having each and every one of</i></p>

<p><i>See, e.g.</i>, '128 USPTO file history, PLJ0000104-536 and more specifically PLJ0000402; PLJ0000439-444 and PLJ0000445-454; PLJ0000475-480 and PLJ0000481-497 especially PLJ0000486, 492 and 497</p> <p>H. G. Brittain, Ed., Polymorphism in Pharmaceutical Solids, p.236, (Marcel Dekker, Inc. 1999), LINEZ-JDG-00000446-449; PLJ0001868-1893, 1891.</p> <p>Brittain, H. Profiles of Drug Substances Excipients, 30: 273-319, 2003, esp. 302-303, PLJ0001925-1948.</p> <p>Brittain, H., Spectroscopy, 16(7): 2001_Harry G. Brittain, PLJ0001917-1921.</p> <p>WO 2011139414 A2, PLJ0001828-1861.</p> <p>U.S. Pharmacopoeia 23 General Ch. 941, PLJ0001803-1804; LINEZ-JDG-00003607-3610.</p> <p>U.S. Pharmacopoeia 26 General Ch. 941, PLJ0001922-1924; LINEZ-JDG-00003615-3619.</p> <p>U.S. Pharmacopoeia 29 General Ch. 941, PLJ0001824-1827.</p> <p>R. Jenkins, R. Snyder, Introduction to X-ray Powder Diffractometry, p. 254-55 (John Wiley & Sons, Inc. 1996), PLJ0001894-1908, 1907-1908.</p> <p>Maccaroni, E. et al, Int. J. Pharm. 351 :144-151 (2008), PLJ0001949-1956.</p>	<p><i>the peaks expressed as 2θ at 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees ± 0.1 degree variance.</i></p> <p>EVIDENCE</p> <p>Defendants will rely on the evidence cited for the terms “characterized by,” “having peaks,” and “about” preceding the XRPD spectrum values</p> <ul style="list-style-type: none"> One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term “characterized by an x-ray powder diffraction having peaks expressed as 2θ at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees.” The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is indefinite and/or means which must include an x-ray powder diffraction having each and every one of the peaks expressed as 2θ at 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees ± 0.1 degree variance. The expert(s) may also rebut arguments presented by Plaintiffs’ expert(s). Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>Wielgus, E. et al, J. Pharm. Sci. (2015), 104(11), 3883-3892 and its Supplemental Information, PLJ0001957-1966.</p> <p>Symed EPO Appeal, LINEZ-JDG-00002135-2179; LINEZ-JDG-00002201-2207.</p> <p>Plaintiffs' Responses to Defendants' Invalidity Contentions at 31, dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by Plaintiffs in regard to the subject terminology, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '128 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the terminology "characterized by an x-ray powder diffraction having peaks expressed as 2θ at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees" in claims 1 and 2 of the '128 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p>	
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Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the terminology "characterized by" in claims 1 and 2 of the '128 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.

Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively "Additional Disclosures"), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the

	<p>Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition an/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants' Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs' Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	
<p>“and further characterized by an IR spectrum having main bands at about 3338, 1742, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm⁻¹ in claims 1 and 2</p>	<p>CONSTRUCTION <i>and further comprising an IR spectrum including bands at approximately 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm⁻¹ (+/- 0.1-10 cm⁻¹ built-in error margin)</i></p> <p>EVIDENCE <i>See, e.g., '128 patent, col. 2, lines 10-14; col. 3, lines 24-28.</i></p> <p><i>See, e.g., '128 file history, PLJ0000439-454, esp. PLJ0000441, 450-451.</i></p> <p>R. Nyquist et. al., The Handbook of Infrared and Raman Spectra of Inorganic Compounds and Organic Salts, Vol. 1, p. 2 (Academic Press 1997), PLJ0001862-1863.</p> <p>H. Szymanski, Ed., Infrared Band Handbook, p. vii-viii (Plenum Press 1963), PLJ0001864-1867</p>	<p>CONSTRUCTION Defendants believe that this long phrase is not a single term and does not need to be separately construed in light of the Court's construction of the terms “and further characterized by”, “having main bands”, and “about” preceding the IR spectrum band values</p> <p>However, if the Court holds that this phrase is not indefinite and must be construed together without separating the individual terms, Defendants propose the following construction: <i>and which must also include an IR spectrum having each and every one of the recited main bands at 3338, 1742, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm⁻¹ within a scientifically acceptable margin of error.</i></p> <p>EVIDENCE Defendants will rely on the evidence cited for the terms “and further characterized by”, “having main bands”, and “about” preceding the IR spectrum band values.</p>

<p>U.S. Pharmacopoeia 37 General Ch. 851, PLJ0001911-1916; U.S. Pharmacopoeia 23 General Ch. 851 LINEZ-JDG-3337-3344.</p> <p>WO 2007/018588, PLJ0002029-2084.</p> <p>US Patent Appln Publication 2006/0142283 A1, PLJ0002005-2028.</p> <p>US Patent 5,688,792, LINEZ-JDG-00000682-694.</p> <p>US Patent 6,444,813, LINEZ-JDG-00000828-831.</p> <p>US Patent 6,559,305, LINEZ-JDG-00000674-677.</p> <p>Brickner, S. et al., J. Med. Chem., 39(3), 673-9 (1996), PLJ0002085-91..</p> <p>US Patent 7,714,128, claims 1 and 2</p> <p>Wielgus, E. et al, J. Pharm. Sci. (2015), 104(11), 3883-3892 and its Supplemental Information, PLJ0001967-1994.</p> <p>Frelek, J. et al., Chem. Comm. (2012), 48(43), 5295-5297 and its Supplemental Information, PLJ0001995-2004.</p> <p>Drugs and the Pharmaceutical Sciences, "Spectroscopy in Pharmaceutical Solids," Bugay, D. and Brittain, H., Taylor and Francis, New York, Chapter 8, 235-270, (2006) (LINEZ-JDG-00000060-95).</p>	<ul style="list-style-type: none"> • One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term "and further characterized by an IR spectrum having main bands at about 3338, 1742, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm⁻¹." The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is indefinite and/or means and which must also include an IR spectrum having each and every one of the recited main bands at 3338, 1742, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm⁻¹ within a scientifically acceptable margin of error. The expert(s) may also rebut arguments presented by Plaintiffs' expert(s). • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>Plaintiffs' Responses to Defendants' Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by Plaintiffs in regard to the subject terminology, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '128 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the terminology "and further characterized by an IR spectrum having main bands at about 3338, 1742, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm⁻¹" in claims 1 and 2 of the '128 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p> <p>Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the terminology "characterized</p>	
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by” in claims 1 and 2 of the ’128 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.

Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be

	permitted by the Court to rely on in, or in support of, or in connection with Defendants' Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs' Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).	
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U.S. PATENT NO. 7,732,597

Claim term	Plaintiffs' Construction and Evidence	Defendants' Construction and Evidence
<p>“A process for preparation of linezolid form III, characterized by peaks in the powder x-ray diffraction spectrum having 2θ angle positions at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees”</p> <p>Preamble in claim 1</p>	<p>CONSTRUCTION</p> <p><i>A method for preparing a crystalline form of linezolid that is different from prior known crystalline forms I and II, comprising an x-ray powder diffraction spectrum including 2θ peaks at approximately 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9, and 29.9 degrees, wherein each peak has a built-in error margin of +/-0.2 degrees</i></p> <p>EVIDENCE</p> <p><i>See e.g., '597 patent col. 2, lines 6-9; col. 3, lines 23-26</i></p> <p><i>See, e.g., '597 file history PLJ0000537-860 and more specifically PLJ0000690-693 and PLJ0000694-725; PLJ 0000705, 710, 715, 720, and 725.</i></p> <p><i>See e.g., '597 patent col. 2, lines 6-9; col. 3, lines 23-26.</i></p> <p><i>See e.g., '597 file history PLJ0000688-725, esp. 690, 699, 705.</i></p> <p>H. G. Brittain, Ed., Polymorphism in Pharmaceutical Solids, p.236, (Marcel Dekker, Inc. 1999), LINEZ-JDG-00000446-449; PLJ0001868-1893, 1891.</p> <p>Brittain, H. Profiles of Drug Substances Excipients, 30: 273-319, 2003, esp. 302-303, PLJ0001925-1948.</p>	<p>CONSTRUCTION</p> <p>Defendants believe that this long phrase is not a single term and does not need to be separately construed in light of the Court's construction of the terms “characterized by,” “having 2θ angle positions,” and “about” preceding the XRPD spectrum values.</p> <p>However, if the Court holds that this phrase is not indefinite and must be construed together without separating the individual terms, Defendants propose the following construction: “A process for preparation of crystalline linezolid polymorph which must include peaks in the powder x-ray diffraction having each and every one of the 2θ angle positions at 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees +/- 0.1 degree variance”</p> <p>EVIDENCE</p> <ul style="list-style-type: none"> Defendants will rely on the evidence cited for the terms “characterized by,” “having 2θ angle positions,” and “about” preceding the XRPD spectrum values. One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term “a process for preparation of linezolid form III, characterized by peaks in the powder x-ray diffraction spectrum having 2θ angle

<p>Brittain, H., Spectroscopy, 16(7): 2001_Harry G. Brittain, PLJ0001917-1921.</p> <p>WO 2011139414 A2, PLJ0001828-1861.</p> <p>U.S. Pharmacopoeia 23 General Ch. 941, PLJ0001803-1804; LINEZ-JDG-00003607-3610.</p> <p>U.S. Pharmacopoeia 26 General Ch. 941, PLJ0001922-1924; LINEZ-JDG-00003615-3619.</p> <p>U.S. Pharmacopoeia 29 General Ch. 941, PLJ0001824-1827.</p> <p>R. Jenkins, R. Snyder, Introduction to X-ray Powder Diffractometry, p. 254-55 (John Wiley & Sons, Inc. 1996), PLJ0001894-1908, 1907-1908.</p> <p>Maccaroni, E. et al, Int. J. Pharm. 351 :144-151 (2008), PLJ0001949-1956.</p> <p>Wielgus, E. et al, J. Pharm. Sci. (2015), 104(11), 3883-3892 and its Supplemental Information, PLJ0001957-1966.</p> <p>Plaintiffs' Responses to Defendants' Invalidity Contentions dated Nov. 4, 2016</p> <p>Symed EPO Appeal, LINEZ-JDG-00002135-2179; LINEZ-JDG-00002201-2207.</p> <p><i>See, e.g.</i>, '128 patent, col. 1, lines 53-62.</p> <p>Plaintiffs' Responses to Defendants' Invalidity Contentions dated Nov. 4, 2016</p>	<p>positions at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees.” The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation should be construed to mean A process for preparation of crystalline linezolid polymorph which must include peaks in the powder x-ray diffraction having each and every one of the 2θ angle positions at 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees +/- 0.1 degree variance. The expert(s) may also rebut arguments presented by Plaintiffs' expert(s).</p> <ul style="list-style-type: none"> • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '597 patent or of any other patent in suit.

Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this subject matter to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the Preamble in claim 1 "A process for preparation of linezolid form III characterized by an x-ray powder diffraction spectrum having peaks expressed as 2θ at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees would be understood by a person of ordinary skill in the art, at the time of the invention, in context, as a unitary expression that limits the claim as a whole. Accordingly, Plaintiffs contest Defendants' Proposed Construction that this is not a single term.

Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the noted terminology in claim 1 of the '597 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.

Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any

<p>other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants’ Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs’ Opening</p>	
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	Markman Submissions, notwithstanding Local Patent Rule No. 4.3(f).	
<p>“about”</p> <p>preceding the XRPD spectrum values in claim 1</p>	<p>CONSTRUCTION <i>approximately</i></p> <p><i>Plaintiffs assert that this term qualifies and should be construed as part of the overall spectrum of XRPD values following it</i></p> <p>EVIDENCE <i>See e.g., ’597 patent col. 2, lines 6-9; col. 3, lines 23-26.</i></p> <p><i>See e.g., ’597 file history PLJ0000688-725, esp. 690, 699, 705.</i></p> <p>H. G. Brittain, Ed., Polymorphism in Pharmaceutical Solids, p.236, (Marcel Dekker, Inc. 1999), LINEZ-JDG-00000446-449; PLJ0001868-1893, 1891.</p> <p>Brittain, H. Profiles of Drug Substances Excipients, 30: 273-319, 2003, esp. 302-303, PLJ0001925-1948.</p> <p>Brittain, H., Spectroscopy, 16(7): 2001_Harry G. Brittain, PLJ0001917-1921.</p> <p>WO 2011139414 A2, PLJ0001828-1861.</p> <p>U.S. Pharmacopoeia 23 General Ch. 941, PLJ0001803-1804; LINEZ-JDG-00003607-3610.</p> <p>U.S. Pharmacopoeia 26 General Ch. 941, PLJ0001922-1924; LINEZ-JDG-00003615-3619.</p> <p>U.S. Pharmacopoeia 29 General Ch. 941, PLJ0001824-1827.</p>	<p>CONSTRUCTION <i>Indefinite</i></p> <p>Alternatively, if the Court determines this term is amenable to construction: <i>no more than a +/- 0.1 degree variance</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • ’597 Patent, claims 1 and 2 • ’597 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 1, ll. 38-53 ○ Col. 2, ll. 6-9 ○ Col. 3, ll. 23-26 • File History of U.S. Pat. Application No. 11/861,406, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 11/861,406 [original claims] ○ 09/26/2007 Preliminary Amendment ○ 08/24/2009 Non-Final Rejection ○ 12/04/2009 Amendment and Request for Reconsideration ○ 03/04/2910 Notice of Allowance • Polymorphism in Pharmaceutical Solids Drugs, “Methods for the Characterization of Polymorphs and Solvates,” Brittain, H., ed., Marcel Dekker, New York, Chapter 6, 236, 227-278, (1999) (LINEZ-JDG-00000008-59). • USP 23 at 1843-44 (LINEZ-JDG-00003607-3610). • USP 26 at 2233-34 (LINEZ-JDG-00003611-3614). • USP 28 at 2514 (LINEZ-JDG-00003615-3619).

	<p>R. Jenkins, R. Snyder, Introduction to X-ray Powder Diffractometry, p. 254-55 (John Wiley & Sons, Inc. 1996), PLJ0001894-1908, 1907-1908.</p> <p>Maccaroni, E. et al, Int. J. Pharm. 351 :144-151 (2008), PLJ0001949-1956.</p> <p>Wielgus, E. et al, J. Pharm. Sci. (2015), 104(11), 3883-3892 and its Supplemental Information, PLJ0001957-1966.</p> <p>Plaintiffs' Responses to Defendants' Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '597 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the term "about" preceding the XRPD spectrum values in claim 1 of the '597 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any)</p>	<ul style="list-style-type: none"> • One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term "about" preceding the XRPD spectrum values in claims 1 and 2. The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is indefinite and/or means no more than a +/- 0.1 degree variance. For example, the expert(s) may testify that consistent with at least the USP and/or knowledge of customary usage by those of ordinary skill in the art 0.1 is the acceptable margin of error of XRPD spectrum values. The expert(s) may also rebut arguments presented by Plaintiffs' expert(s). • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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are contrary to other evidence and/or the weight of the evidence.

Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the term "about" preceding the XRPD spectrum values in claim 1 of the '597 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.

Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively "Additional Disclosures"), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such

	Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition an/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants' Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs' Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).	
<p>"having 2θ angle positions"</p> <p>in claim 1</p>	<p>CONSTRUCTION <i>including peaks</i></p> <p>EVIDENCE <i>See also e.g., '597 patent col. 2, lines 6-9; col. 3, lines 23-26</i></p> <p><i>See e.g., '597 file history PLJ0000688-725, esp. 690, 699, 705.</i></p> <p>Symed EPO Appeal, LINEZ-JDG-00002135-2179; LINEZ-JDG-00002201-2207.</p> <p>Plaintiffs' Responses to Defendants' Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '597 patent or of any other patent in suit.</p>	<p>CONSTRUCTION <i>having each and every one of the 2θ angle positions</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • '597 Patent, claims 1 and 2 • '597 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 1, ll. 38-53 ○ Col. 2, ll. 6-9 ○ Col. 3, ll. 23-26 • File History of U.S. Pat. Application No. 11/861,406, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 11/861,406 [original claims] ○ 09/26/2007 Preliminary Amendment ○ 08/24/2009 Non-Final Rejection ○ 12/04/2009 Amendment and Request for Reconsideration ○ 03/04/2910 Notice of Allowance • Ann W. Newman and G. Patrick Stahly, Form Selection of Pharmaceutical Compounds, Marcel Decker (2002) (LINEZ-JDG-00003421-3477).

	<p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the terminology "having 2θ angle positions" in claim 1 of the '597 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p> <p>Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the term "about" preceding the XRPD spectrum values in claim 1 of the '597 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as</p>	<ul style="list-style-type: none"> • Harry G. Brittain, Profiles of Drug Substances, Excipients and Related Methodology, Vol. 30, (2003) (LINEZ-JDG-00003620-68). • One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term "having 2θ angle positions." The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is means having each and every one of the 2θ angle positions. For example, the expert(s) may testify that consistent with at least the prosecution history and/or knowledge of customary usage by those of ordinary skill in the art, all recited XRPD peaks should be present for a given polymorph. The expert(s) may also rebut arguments presented by Plaintiffs' expert(s). • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants’ Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs’ Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	
<p>“characterized by” in claim 1</p>	<p>CONSTRUCTION <i>comprising</i></p> <p>EVIDENCE <i>See also e.g., ’597 patent col. 2, lines 6-9; col. 3, lines 23-26.</i></p> <p><i>See e.g., ’597 file history PLJ0000688-725, esp. 690, 699, 705.</i></p> <p>Plaintiffs’ Responses to Defendants’ Invalidity Contentions dated Nov. 4, 2016</p>	<p>CONSTRUCTION <i>which must include</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • ’597 Patent, claims 1 and 2 • ’597 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 2, ll. 6-9 ○ Col. 3, ll. 23-26 • File History of U.S. Pat. Application No. 11/861,406, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 11/861,406 [original claims] ○ 09/26/2007 Preliminary Amendment

<p>Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '597 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the terminology "characterized by" in claim 1 of the '597 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p> <p>Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the term "characterized by" in claim 1 of the '597 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all</p>	<ul style="list-style-type: none"> ○ 08/24/2009 Non-Final Rejection ○ 12/04/2009 Amendment and Request for Reconsideration ○ 03/04/2010 Notice of Allowance ● One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term "characterized by." The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is means which must include. For example, the expert(s) may testify that consistent with at least the prosecution history and/or knowledge of customary usage by those of ordinary skill in the art, the XRPD spectrum of a given polymorph must have the recited XRPD peaks of that polymorph. The expert(s) may also rebut arguments presented by Plaintiffs' expert(s). ● Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants’ Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs’ Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	
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U.S. PATENT NO. 7,718,799

Claim term	Plaintiffs' Construction and Evidence	Defendants' Construction and Evidence
<p>“A process for preparation of linezolid form III characterized by an x-ray powder diffraction spectrum having peaks expressed as 2θ at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees, wherein the crystalline linezolid form III is further characterized by an IR spectrum having main bands at about 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm^{-1}”</p>	<p>CONSTRUCTION <i>A method for preparing a crystalline form of linezolid that is different from prior known crystalline forms I and II, comprising an x-ray powder diffraction spectrum including 2θ peaks at approximately 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9, and 29.9 degrees, wherein each peak has a built-in error margin of ± 0.2 degrees; and comprising an IR spectrum including bands at approximately 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm^{-1} (± 0.1-10 cm^{-1})</i></p> <p>EVIDENCE <i>See</i> '799 patent col. 2, lines 6-9 and col. 3, lines 23-26. '799 file history PLJ0001325-1358; PLJ0001374-1382. H. G. Brittain, Ed., Polymorphism in Pharmaceutical Solids, p.236, (Marcel Dekker, Inc. 1999), LINEZ-JDG-00000446-449; PLJ0001868-1893, 1891. Brittain, H. Profiles of Drug Substances Excipients, 30: 273-319, 2003, esp. 302-303, PLJ0001925-1948. Brittain, H., Spectroscopy, 16(7): 2001_Harry G. Brittain, PLJ0001917-1921. Symed EPO Appeal, LINEZ-JDG-00002135-2179; LINEZ-JDG-00002201-2207.</p>	<p>CONSTRUCTION</p> <p>Defendants believe that this long phrase is not a single term and does not need to be separately construed in light of the Court's construction of the terms “characterized by”, “having peaks,” “is further characterized by,” “having main bands,” “about” preceding the XRPD spectrum values, and “about” preceding the XRPD spectrum values and IR spectrum values.</p> <p>However, if the Court holds that this phrase is not indefinite and must be construed together without separating the individual terms, Defendants propose the following construction: “A process for preparation of linezolid form III which must include an x-powder diffraction spectrum having each and every one of the peaks expressed as 2θ at 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees ± 0.1 degree variance, wherein the crystalline linezolid form III must include an IR spectrum having each and every one of the main bands at 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm^{-1} with a scientifically acceptable margin of error”</p>

Preamble in claim 1	<p>WO 2011139414 A2, PLJ0001828-1861.</p> <p>U.S. Pharmacopoeia 23 General Ch. 941, PLJ0001803-1804.</p> <p>U.S. Pharmacopoeia 26 General Ch. 941, PLJ0001922-1924; LINEZ-JDG-00003615-3619.</p> <p>U.S. Pharmacopoeia 29 General Ch. 941, PLJ0001824-1827.</p> <p>R. Jenkins, R. Snyder, Introduction to X-ray Powder Diffractometry, p. 254-55 (John Wiley & Sons, Inc. 1996), PLJ0001894-1908, 1907-1908.</p> <p>Maccaroni, E. et al, Int. J. Pharm. 351 :144-151 (2008), PLJ0001949-1956.</p> <p>Wielgus, E. et al, J. Pharm. Sci. (2015), 104(11), 3883-3892 and its Supplemental Information, PLJ0001957-1966. <i>See also</i> '799 patent col. 2, lines 6-9 and col. 3, lines 23-26.</p> <p>R. Nyquist et. al., The Handbook of Infrared and Raman Spectra of Inorganic Compounds and Organic Salts, Vol. 1, p. 2 (Academic Press 1997), PLJ0001862-1863.</p> <p>H. Szymanski, Ed., Infrared Band Handbook, p. vii-viii (Plenum Press 1963), PLJ0001864-1867</p> <p>U.S. Pharmacopoeia 37 General Ch. 851, PLJ0001911-1916; U.S. Pharmacopoeia 23 General Ch. 851 LINEZ-JDG-3337-3344.</p> <p>WO 2007/018588, PLJ0002029-2084.</p>	<p>EVIDENCE</p> <ul style="list-style-type: none"> Defendants will rely on the evidence cited for the terms “characterized by”, “having peaks,” “is further characterized by,” “having main bands,” “about” preceding the XRPD spectrum values, and “about” preceding the XRPD spectrum values and IR spectrum values. One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term “process for preparation of linezolid form III characterized by an x-ray powder diffraction spectrum having peaks expressed as 2θ at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees, wherein the crystalline linezolid form III is further characterized by an IR spectrum having main bands at about 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm⁻¹.” The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation should be construed to mean a process for preparation of linezolid form III which must include an x-powder diffraction spectrum having each and every one of the peaks expressed as 2θ at 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees +/- 0.1 degree variance, wherein the crystalline linezolid form III must include an IR spectrum having each and every one of the main bands at 3338, 1741, 1662, 1544, 1517, 1471, 1452, 1425, 1400, 1381, 1334, 1273, 1255, 1228, 1213, 1197, 1176, 1116, 1082, 1051, 937, 923, 904, 869, 825 and 756 cm⁻¹ with a scientifically acceptable
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	<p>US Patent Appln Publication 2006/0142283 A1, PLJ0002005-2028.</p> <p>US Patent 5,688,792, LINEZ-JDG-00000682-694.</p> <p>US Patent 6,444,813, LINEZ-JDG-00000828-831.</p> <p>US Patent 6,559,305, LINEZ-JDG-00000674-677.</p> <p>Brickner, S. et al., J. Med. Chem., 39(3), 673-9 (1996), PLJ0002085-91..</p> <p>US Patent 7,714,128, claims 1 and 2</p> <p>Wielgus, E. et al, J. Pharm. Sci. (2015), 104(11), 3883-3892 and its Supplemental Information, PLJ0001967-1994.</p> <p>Frelek, J. et al., Chem. Comm. (2012), 48(43), 5295-5297 and its Supplemental Information, PLJ0001995-2004.</p> <p>Drugs and the Pharmaceutical Sciences, “Spectroscopy in Pharmaceutical Solids,” Bugay, D. and Brittain, H., Taylor and Francis, New York, Chapter 8, 235-270, (2006) (LINEZ-JDG-00000060-95).</p> <p><i>See, e.g.</i>, ’128 patent, col. 1, lines 53-62.</p> <p>Plaintiffs’ Responses to Defendants’ Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants’ construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in</p>	<p>margin of error.. The expert(s) may also rebut arguments presented by Plaintiffs’ expert(s).</p> <ul style="list-style-type: none"> • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '799 patent or of any other patent in suit.

Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this subject matter to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the Preamble in claim 1 "A process for preparation of linezolid form III characterized by an x-ray powder diffraction spectrum having peaks expressed as 2θ at about 7.6, 9.6, 13.6, 14.9, 18.2, 18.9, 21.2, 22.3, 25.6, 26.9, 27.9 and 29.9 degrees would be understood by a person of ordinary skill in the art, at the time of the invention, in context, as a unitary expression that limits the claim as a whole. Accordingly, Plaintiffs contest Defendants' Proposed Construction that this is not a single term.

See above position for Plaintiffs as to defendants' constructions of "characterized by", "having peaks," "further characterized by," "having main bands," Plaintiffs oppose Defendants' construction to the extent to which it contravenes Plaintiffs' construction of any/all terms in the Asserted Claims of the Asserted Patents. Plaintiffs further contend that Asserted Claims in the '799 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.

Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the noted terminology in claim 1 of the '799 Patent and how

such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.

Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants’ Opening *Markman* Submissions and/or in opposition or in rebuttal to Plaintiffs’ Opening

	Markman Submissions, notwithstanding Local Patent Rule No. 4.3(f).	
<p>“about”</p> <p>preceding the XRPD spectrum values in claim 1</p>	<p>CONSTRUCTION <i>approximately</i></p> <p><i>Plaintiffs assert that this term qualifies and should be construed as part of the overall spectrum of XRPD values following it</i></p> <p>EVIDENCE <i>See</i> ’799 patent col. 2, lines 6-9 and col. 3, lines 23-26.</p> <p>’799 file history PLJ0001325-1358; PLJ0001374-1382.</p> <p>H. G. Brittain, Ed., Polymorphism in Pharmaceutical Solids, p.236, (Marcel Dekker, Inc. 1999), LINEZ-JDG-00000446-449; PLJ0001868-1893, 1891.</p> <p>Brittain, H. Profiles of Drug Substances Excipients, 30: 273-319, 2003, esp. 302-303, PLJ0001925-1948.</p> <p>Brittain, H., Spectroscopy, 16(7): 2001_Harry G. Brittain, PLJ0001917-1921.</p> <p>WO 2011139414 A2, PLJ0001828-1861.</p> <p>U.S. Pharmacopoeia 23 General Ch. 941, PLJ0001803-1804; LINEZ-JDG-00003607-3610.</p> <p>U.S. Pharmacopoeia 26 General Ch. 941, PLJ0001922-1924; LINEZ-JDG-00003615-3619.</p> <p>U.S. Pharmacopoeia 29 General Ch. 941, PLJ0001824-1827.</p>	<p>CONSTRUCTION <i>Indefinite</i> Alternatively, if the Court determines this term is amenable to construction: <i>no more than a +/- 0.1 degree variance</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • ’799 Patent, claim 1 • ’799 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 1, ll. 38-53 ○ Col. 2, ll. 6-9 ○ Col. 3, ll. 23-26 • File History of U.S. Pat. Application No. 11/861,340, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 11/861,340 [original claims] ○ 09/26/2007 Preliminary Amendment ○ 3/7/2008 Amendment and Request for Reconsideration ○ 4/1/2008 Non-Final Rejection ○ 9/10/2008 Amendment and Request for Reconsideration ○ 12/17/2008 Final Rejection ○ 04/02/2009 Amendment ○ 04/21/2009 Advisory Action ○ 07/21/2009 Supplemental Amendment ○ 10/05/2009 Final Rejection ○ 12/04/2009 Amendment ○ 12/21/2009 Advisory Action ○ 12/21/2009 Amendment ○ 12/21/2009 Supplemental Amendment ○ 1/14/2009 Advisory Action

	<p>R. Jenkins, R. Snyder, Introduction to X-ray Powder Diffractometry, p. 254-55 (John Wiley & Sons, Inc. 1996), PLJ0001894-1908, 1907-1908.</p> <p>Maccaroni, E. et al, Int. J. Pharm. 351 :144-151 (2008), PLJ0001949-1956.</p> <p>Wielgus, E. et al, J. Pharm. Sci. (2015), 104(11), 3883-3892 and its Supplemental Information, PLJ0001957-1966.</p> <p>Plaintiffs' Responses to Defendants' Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '799 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the term "about" preceding the XRPD spectrum values in claim 1 of the '799 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p>	<ul style="list-style-type: none"> ○ 03/25/2010 Supplemental Amendment ○ 03/25/2010 Notice of Allowance • Polymorphism in Pharmaceutical Solids Drugs, "<i>Methods for the Characterization of Polymorphs and Solvates</i>," Brittain, H., ed., Marcel Dekker, New York, Chapter 6, 236, 227-278, (1999) (LINEZ-JDG-00000008-59). • USP 23 at 1843-44 (LINEZ-JDG-00003607-3610). • USP 26 at 2233-34 (LINEZ-JDG-00003611-3614). • USP 28 at 2514 (LINEZ-JDG-00003615-3619). • One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term "about" preceding the XRPD spectrum values in claims 1 and 2. The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is indefinite and/or means no more than a +/- 0.1 degree variance. For example, the expert(s) may testify that consistent with at least the USP and/or knowledge of customary usage by those of ordinary skill in the art 0.1 is the acceptable margin of error of XRPD spectrum values. The expert(s) may also rebut arguments presented by Plaintiffs' expert(s). • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the term "about" preceding the XRPD spectrum values in claim 1 of the '799 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively "Additional Disclosures"), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond</p>	
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	in kind by way of opposition an/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants' Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs' Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).	
“about” preceding the IR spectrum band values in claim 1	<p>CONSTRUCTION <i>approximately</i></p> <p><i>Plaintiffs assert that this term qualifies and should be construed as part of the overall spectrum of IR values following it</i></p> <p>EVIDENCE See also '799 patent col. 2, lines 6-9 and col. 3, lines 23-26. '799 file history PLJ0001325-1358; PLJ0001374-1382. R. Nyquist et. al., The Handbook of Infrared and Raman Spectra of Inorganic Compounds and Organic Salts, Vol. 1, p. 2 (Academic Press 1997), PLJ0001862-1863. H. Szymanski, Ed., Infrared Band Handbook, p. vii-viii (Plenum Press 1963), PLJ0001864-1867 U.S. Pharmacopoeia 37 General Ch. 851, PLJ0001911-1916; U.S. Pharmacopoeia 23 General Ch. 851 LINEZ-JDG-3337-3344. WO 2007/018588, PLJ0002029-2084. US Patent Appln Publication 2006/0142283 A1, PLJ0002005-2028.</p>	<p>CONSTRUCTION <i>Indefinite</i> Alternatively, if the Court determines this term is amenable to construction: <i>a scientifically acceptable margin of error</i></p> <p>EVIDENCE '799 Patent, claim 1</p> <ul style="list-style-type: none"> • '799 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 1, ll. 38-53 ○ Col. 2, ll. 10-14 ○ Col. 3, ll. 27-31 • File History of U.S. Pat. Application No. 11/861,340, including <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 11/861,340 [original claims] ○ 09/26/2007 Preliminary Amendment ○ 3/7/2008 Amendment and Request for Reconsideration ○ 4/1/2008 Non-Final Rejection ○ 9/10/2008 Amendment and Request for Reconsideration ○ 12/17/2008 Final Rejection ○ 04/02/2009 Amendment ○ 04/21/2009 Advisory Action ○ 07/21/2009 Supplemental Amendment ○ 10/05/2009 Final Rejection ○ 12/04/2009 Amendment

	<p>US Patent 5,688,792, LINEZ-JDG-00000682-694.</p> <p>US Patent 6,444,813, LINEZ-JDG-00000828-831.</p> <p>US Patent 6,559,305, LINEZ-JDG-00000674-677.</p> <p>Brickner, S. et al., J. Med. Chem., 39(3), 673-9 (1996), PLJ0002085-91..</p> <p>US Patent 7,714,128, claims 1 and 2</p> <p>Wielgus, E. et al, J. Pharm. Sci. (2015), 104(11), 3883-3892 and its Supplemental Information, PLJ0001967-1994.</p> <p>Frelek, J. et al., Chem. Comm. (2012), 48(43), 5295-5297 and its Supplemental Information, PLJ0001995-2004.</p> <p>Drugs and the Pharmaceutical Sciences, “Spectroscopy in Pharmaceutical Solids,” Bugay, D. and Brittain, H., Taylor and Francis, New York, Chapter 8, 235-270, (2006) (LINEZ-JDG-00000060-95).</p> <p>Plaintiffs’ Responses to Defendants’ Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants’ construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs’ construction of the subject term or any other term(s) in claims of the ‘799 patent or of any other patent in suit.</p>	<ul style="list-style-type: none"> ○ 12/21/2009 Advisory Action ○ 12/21/2009 Amendment ○ 12/21/2009 Supplemental Amendment ○ 1/14/2009 Advisory Action ○ 03/25/2010 Supplemental Amendment ○ 03/25/2010 Notice of Allowance ● Plaintiffs’ Responses to Defendants’ Invalidity Contentions at 31, dated Nov. 4, 2016. ● Drugs and the Pharmaceutical Sciences, “Spectroscopy in Pharmaceutical Solids,” Bugay, D. and Brittain, H., Taylor and Francis, New York, Chapter 8, 235-270, (2006) (LINEZ-JDG-00000060- 95). ● Preformulation in Solid Dosage Form Development, “Spectroscopic Methods for the Characterization of Drug Substances,” Adeyeye, M and Brittain, H., eds., CRC Press, Chapter 3.5, 253–277 (2008) (LINEZ-JDG-00003396-3420). ● Polymorphism in Pharmaceutical Solids Drugs, “Methods for the Characterization of Polymorphs and Solvates,” Brittain, H., ed., Marcel Dekker, New York, Chapter 6, 227-278 (1999) (LINEZJDG-00000008-59). ● USP 23 at 1834 (LINEZ-JDG-00003337-3344). ● USP 39 at 718-19 (LINEZ-JDG-00003602-3606). ● One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term “about” preceding the IR spectrum band values in claims 1 and 2. The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is indefinite and/or means a scientifically acceptable margin of error. For example, the expert(s) may testify that
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	<p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the term "about" preceding the IR spectrum band values in claim 1 of the '799 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p> <p>Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the term "about" preceding the IR spectrum band values in claim 1 of the '799 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or</p>	<p>consistent with at least the USP and/or knowledge of customary usage by those of ordinary skill in the art, the scientifically acceptable margin of error of IR spectrum values depends on various parameters in the sample preparation and measurements. The expert(s) may also rebut arguments presented by Plaintiffs' expert(s).</p> <ul style="list-style-type: none"> • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants’ Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs’ Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	
<p>“characterized by” in claim 1</p>	<p>CONSTRUCTION <i>comprising</i></p> <p>EVIDENCE <i>See also</i> ’799 patent col. 2, lines 6-9 and col. 3, lines 23-26. ’799 file history PLJ0001325-1358; PLJ0001374-1382. Plaintiffs’ Responses to Defendants’ Invalidity Contentions dated Nov. 4, 2016 Plaintiffs reserve the right to rely, in opposition to Defendants’ construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by</p>	<p>CONSTRUCTION <i>which must include</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • ’799 Patent, claim 1 • ’799 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 2, ll. 6-9 ○ Col. 3, ll. 23-26 • File History of U.S. Pat. Application No. 11/861,304, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 11/861,304 [original claims] ○ 09/26/2007 Preliminary Amendment ○ 03/07/2008 Amendment

	<p>Defendants in support of their own constructions or in opposition to Plaintiffs’ construction of the subject term or any other term(s) in claims of the ‘799 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants’ construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the term “characterized by” in claim 1 of the ‘799 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants’ proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p> <p>Plaintiffs’ expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the term “characterized by” in claim 1 of the ‘799 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in</p>	<ul style="list-style-type: none"> ○ 04/01/2008 Non-Final Rejection ○ 9/10/2008 Amendment ○ 12/17/2008 Final Rejection ○ 04/02/2009 Amendment ○ 04/21/2009 Advisory Action ○ 07/21/2009 Supplemental Amendment ○ 10/05/2009 Final Rejection ○ 12/04/2009 Amendment ○ 12/21/2009 Advisory Action ○ 12/21/2009 Amendment ○ 12/21/2009 Supplemental Amendment ○ 1/14/2009 Advisory Action ○ 03/25/2010 Supplemental Amendment ○ 03/25/2010 Notice of Allowance ● One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term “characterized by.” The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is means which must include. For example, the expert(s) may testify that consistent with at least the prosecution history and/or knowledge of customary usage by those of ordinary skill in the art, the XRPD spectrum of a given polymorph must have the recited XRPD peaks of that polymorph. The expert(s) may also rebut arguments presented by Plaintiffs’ expert(s). ● Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants’ Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs’ Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	
<p>“having peaks” in claim 1</p>	<p>CONSTRUCTION <i>including peaks</i></p> <p>EVIDENCE <i>See also</i> ’799 patent col. 2, lines 6-9 and col. 3, lines 23-26. ’799 file history PLJ0001325-1358; PLJ0001374-1382.</p>	<p>CONSTRUCTION <i>having each and every one of the peaks</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • ’799 Patent, claim 1 • ’799 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 1, ll. 38-53 ○ Col. 2, ll. 6-9 ○ Col. 3, ll. 23-26

	<p>Symed EPO Appeal, LINEZ-JDG-00002135-2179; LINEZ-JDG-00002201-2207.</p> <p>Plaintiffs' Responses to Defendants' Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants' construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs' construction of the subject term or any other term(s) in claims of the '799 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants' construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the term "having peaks" in claim 1 of the '799 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants' proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p> <p>Plaintiffs' expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the term "having peaks" in claim 1 of the '799 Patent and how such understanding would be contrary to any understanding</p>	<ul style="list-style-type: none"> • File History of U.S. Pat. Application No. 11/861,304, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 11/861,304 [original claims] ○ 09/26/2007 Preliminary Amendment ○ 03/07/2008 Amendment ○ 04/01/2008 Non-Final Rejection ○ 9/10/2008 Amendment ○ 12/17/2008 Final Rejection ○ 04/02/2009 Amendment ○ 04/21/2009 Advisory Action ○ 07/21/2009 Supplemental Amendment ○ 10/05/2009 Final Rejection ○ 12/04/2009 Amendment ○ 12/21/2009 Advisory Action ○ 12/21/2009 Amendment ○ 12/21/2009 Supplemental Amendment ○ 1/14/2009 Advisory Action ○ 03/25/2010 Supplemental Amendment ○ 03/25/2010 Notice of Allowance • Ann W. Newman and G. Patrick Stahly, Form Selection of Pharmaceutical Compounds, Marcel Decker (2002) (LINEZ-JDG-00003421-3477). • Harry G. Brittain, Profiles of Drug Substances, Excipients and Related Methodology, Vol. 30 (2003) (LINEZ-JDG-00003620-3668). • One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term "having peaks." The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is means having each and every one of the peaks. For
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	<p>offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”), should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants’ Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs’ Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	<p>example, the expert(s) may testify that consistent with at least the prosecution history and/or knowledge of customary usage by those of ordinary skill in the art, all recited XRPD peaks should be present for a given polymorph. The expert(s) may also rebut arguments presented by Plaintiffs’ expert(s).</p> <ul style="list-style-type: none"> • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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<p>“is further characterized by”</p> <p>in claim 1</p>	<p>CONSTRUCTION <i>and further comprising</i></p> <p>EVIDENCE <i>See also</i> ’799 patent col. 2, lines 10-14; col. 3, lines 27-31.</p> <p>Plaintiffs’ Responses to Defendants’ Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants’ construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs’ construction of the subject term or any other term(s) in claims of the ’799 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants’ construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the intrinsic record and/or other evidence, including without limitation, that the term “further characterized by” in claim 1 of the ’799 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants’ proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p> <p>Plaintiffs’ expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the</p>	<p>CONSTRUCTION <i>must also include</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • ’799 Patent, claim 1 • ’799 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 2, ll. 10-14 ○ Col. 3, ll. 27-31 • File History of U.S. Pat. Application No. 11/861,304, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 11/861,304 [original claims] ○ 09/26/2007 Preliminary Amendment ○ 03/07/2008 Amendment ○ 04/01/2008 Non-Final Rejection ○ 9/10/2008 Amendment ○ 12/17/2008 Final Rejection ○ 04/02/2009 Amendment ○ 04/21/2009 Advisory Action ○ 07/21/2009 Supplemental Amendment ○ 10/05/2009 Final Rejection ○ 12/04/2009 Amendment ○ 12/21/2009 Advisory Action ○ 12/21/2009 Amendment ○ 12/21/2009 Supplemental Amendment ○ 1/14/2009 Advisory Action ○ 03/25/2010 Supplemental Amendment ○ 03/25/2010 Notice of Allowance • One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term “is further characterized by.” The expert(s) will testify that, based upon and/or consistent with the specification, prosecution
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	<p>term “further characterized by” in claim 1 of the ‘799 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p>	<p>history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is means must also include. For example, the expert(s) may testify that consistent with at least the prosecution history and/or knowledge of customary usage by those of ordinary skill in the art, the IR spectrum of a given polymorph must have the recited IR bands of that polymorph. The expert(s) may also rebut arguments presented by Plaintiffs’ expert(s).</p> <ul style="list-style-type: none"> • Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
<p>“having main bands”</p> <p>in claim 1</p>	<p>CONSTRUCTION <i>including the following main bands</i></p> <p>EVIDENCE <i>See also</i> ‘799 patent col. 2, lines 10-14; col. 3, lines 27-31.</p> <p>Plaintiffs’ Responses to Defendants’ Invalidity Contentions dated Nov. 4, 2016</p> <p>Plaintiffs reserve the right to rely, in opposition to Defendants’ construction, on evidence relied on by Plaintiffs in regard to the subject term, or on any evidence relied on by Defendants in support of their own constructions or in opposition to Plaintiffs’ construction of the subject term or any other term(s) in claims of the ‘799 patent or of any other patent in suit.</p> <p>Plaintiffs may also rely, in opposition to Defendants’ construction, on the expert opinion of one or more experts concerning the meaning of this term to a person of ordinary skill in the art at the time of the invention in light of the</p>	<p>CONSTRUCTION <i>having each and every one of the recited main bands</i></p> <p>EVIDENCE</p> <ul style="list-style-type: none"> • ‘799 Patent, claim 1 • ‘799 Patent specification, including: <ul style="list-style-type: none"> ○ Col. 1, ll. 38-53 ○ Col. 2, ll. 10-14 ○ Col. 3, ll. 27-31 • File History of U.S. Pat. Application No. 11/861,304, including: <ul style="list-style-type: none"> ○ Claims of U.S. Patent Application 11/861,304 [original claims] ○ 09/26/2007 Preliminary Amendment ○ 03/07/2008 Amendment ○ 04/01/2008 Non-Final Rejection ○ 9/10/2008 Amendment ○ 12/17/2008 Final Rejection ○ 04/02/2009 Amendment ○ 04/21/2009 Advisory Action

	<p>intrinsic record and/or other evidence, including without limitation, that the term “having main bands” in claim 1 of the ‘799 Patent and in any other Asserted Claim would have the meaning that Plaintiffs have proposed or a meaning contrary to that offered by Defendants. Experts for Plaintiffs may also offer one or more opinions that Defendants’ proposed construction(s) (if any) are contrary to other evidence and/or the weight of the evidence.</p> <p>Plaintiffs’ expert testimony may include the expert opinion of one or more experts concerning the qualifications and knowledge of a person of ordinary skill in the art at the time of the invention and how such a person would understand the term “having main bands” in claim 1 of the ‘799 Patent and how such understanding would be contrary to any understanding offered by Defendants and/or expert opinions offered by Defendants.</p> <p>Furthermore, Plaintiffs expressly reserve the right to rely on expert or other technical/scientific testimony or any other information in further support of or in connection with their proposed construction of the subject term/phrase and any/all other terms or phrases in the Asserted Claims of the Asserted Patents, and/or in opposition to or in rebuttal to any such testimony or information relied upon by Defendants for or in connection with such purpose, including, but not limited to, any/all proposed testimony of any kind and/or information newly added to the present document by Defendants with their edits/additions to the same made on January 12, 2017, as well as any/all other proposed testimony of any kind and/or information newly presented by Defendants after service of their documents containing the information required to have been disclosed under Local Patent Rule Nos. 4.2(a), 4.2(b), and 4.2(c), inclusive (collectively “Additional Disclosures”),</p>	<ul style="list-style-type: none"> ○ 07/21/2009 Supplemental Amendment ○ 10/05/2009 Final Rejection ○ 12/04/2009 Amendment ○ 12/21/2009 Advisory Action ○ 12/21/2009 Amendment ○ 12/21/2009 Supplemental Amendment ○ 1/14/2009 Advisory Action ○ 03/25/2010 Supplemental Amendment ○ 03/25/2010 Notice of Allowance ● Puligandla Viswanadham and Pratap Singh, FAILURE MODES AND MECHANISMS IN ELECTRONIC PACKAGES, at 114 (1998) (LINEZ-JDG-00003345-3395). ● Phillip Crews et al., ORGANIC STRUCTURE ANALYSIS, Oxford University Press, at 329 (1998) (LINEZ-JDG-00003567-3601). ● One or more experts with a background in chemistry and/or material science may provide testimony relating to the proper construction of the claim term “having main bands.” The expert(s) will testify that, based upon and/or consistent with the specification, prosecution history, and/or extrinsic evidence, and based upon knowledge of customary usage by those of ordinary skill in the art, this claim limitation is means having each and every one of the recited main bands. For example, the expert(s) may testify that consistent with at least the prosecution history and/or knowledge of customary usage by those of ordinary skill in the art, all distinctive IR bands should be present for a given polymorph. The expert(s) may also rebut arguments presented by Plaintiffs’ expert(s). ● Pursuant to the Scheduling Order and L. Pat. R. 4.5, Defendants will provide expert certifications and/or declarations with their opening and/or responding <i>Markman</i> briefs.
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	<p>should the Court determine to consider any such Additional Disclosures. While Plaintiffs do not currently believe the Court should deem any expert or other testimony to be necessary or helpful in determining the proper construction of any of the terms/phrases in the Asserted Claims of the Asserted Patents and while Plaintiffs believe any such Additional Disclosures by Defendants to be improper, at least without leave of court, Plaintiffs nonetheless wish to preserve their option, their right, and their ability to reasonably respond in kind by way of opposition and/or rebuttal to any such Additional Disclosures as Defendants may rely on or be permitted by the Court to rely on in, or in support of, or in connection with Defendants' Opening <i>Markman</i> Submissions and/or in opposition or in rebuttal to Plaintiffs' Opening <i>Markman</i> Submissions, notwithstanding Local Patent Rule No. 4.3(f).</p>	
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